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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K111267**

Applicant information:

Date Prepared:	September 23, 2011
Name: Address	**ABB CONCISE Optical Group, LLC** 1750 N. Loop Road Ste #150 Alameda, CA 94502
Contact Person:	Ms. Lynda Baker Executive Vice President
Phone number:	(510) 483 9400
FDA Consultant:	Martin Dalsing Medvice Consulting, Inc. 806 Kimball Avenue Grand Junction, CO 81501
Phone number	(970) 243-5490

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**CONCISE, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)**

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Equivalent Devices:

The **CONCISE,** Silicone Hydrogel Daily Wear Soft Contact Lenses (efrofilcon A) are substantially equivalent to the following predicate devices:

Predicate devices:

"IntelliWave^3", Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)"
by Art Optical Contact Lens, Inc.
510(k) number: **K100221**

"**Biofinity (comfilcon A)**"
by Coopervision, Inc.
510(k) number; **K052560**

"ActiFresh 400 (lidofilcon A)"
By Hydron Ltd.
510(k) number: **K983637**

Device Description:

The **CONCISE** Silicone Hydrogel Soft Contact Lenses are fabricated from efrofilcon A, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (efrofilcon A) is a daily wear silicone hydrogel contact lens that is not surface treated and characterized by a high water content. The lens material is composed of silicone monomers cross linked with other monomers and optionally incorporates D&C Green 6 as an integrated handling tint. The lenses are made by lathe-cut for custom RX. It consists of 26% efrofilcon A and 74% water by weight when immersed in a buffered saline solution. The (efrofilcon A) name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (efrofilcon A) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

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The Physical properties of the lens are:

Refractive Index	1.38
Light Transmission	greater than 97%
Surface Character	hydrophilic
Water Content	74 %
Specific Gravity	1.048 (hydrated)
Oxygen Permeability	59.8×10^{-11} (cm^2/sec) (ml O_2/ml x hPa @ 35°C), (revised Fatt method).

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 74% water by weight. The lenses will be manufactured in spherical, aspherical, toric, multifocal, multifocal toric and irregular Cornea configurations with the following features and properties.

• Chord Diameter	12.0 mm to 16.00 mm
• Center Thickness	0.01 mm to 0.50 mm
• Base Curve	8.0 mm to 9.5 mm
• Power Range	-20.00D to +20.00D in 0.25 steps
• Cylinder Power (Toric)	-0.25D to -12.00D
• Cylinder Power (Multifocal Toric)	-0.25D to -4.00D
• Add Power (Multifocal)	+0.50D to +4.00D

The lens is supplied sterile in vials containing a buffered saline solution. Vial labeling is printed with appropriate lot numbering, expiration dating and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

Intended Use:

The **CONCISE,** sphere (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **CONCISE,** toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 12 diopters.

The **CONCISE,** multifocal (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding .75 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **CONCISE,** multifocal toric (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **CONCISE**, irregular cornea (efrofilcon A) Silicone Hydrogel Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons and may be prescribed in otherwise non-diseased eyes that require a Soft Contact Lens for the management of irregular corneal conditions such as keratoconus and post graft fitting.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system or hydrogen peroxide disinfection systems.

Testing:

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **CONCISE** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses packaged in glass vials. All non-clinical toxicology tests were conducted in accordance with the GLP regulation.

Tests performed and results are as follows:

Cytotoxicity, MEM Elution Test, ISO	Non-Cytotoxic
Ocular Irritation Test ISO	PASS, Non irritant to ocular surface
Acute Systemic Toxicity Test ISO	PASS, negative

A series of verification bench studies were conducted to demonstrate the efficacy of the manufacturing processes on various lens parameters and characteristics. All bench studies were conducted according to CGMP procedures and protocols.

Tests performed and results are as follows:

Diameter, base curve - dry/wet	PASS, within ANSI specification
Power – dry/wet	PASS, within ANSI specification
Optical quality/clarity	PASS, within ANSI specification
Process repeatability	PASS, within tolerance

A series of sterility and package integrity tests were performed to establish the sterility and shelf life of the product. All tests were performed according USP standards.

Tests performed and results are as follows:

Sterility	PASS, sterile product
Package integrity	PASS, sterile product

SUMMARY of Non clinical testing results: the non-clinical testing on the **CONCISE** (efrofilcon A) Silicone Hydrogel Soft Contact Lenses demonstrate that:

- Lenses supplied in glass vials are sterile for the indicated shelf-life,
- The packaging material and extracts are not toxic and not irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Data

The clinical performance of the (efrofilcon A) lens material has been previously established, and therefore was not required for this 510(k).

The **CONCISE,** (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens is identical to the cleared Intelliwave[3] (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens, cleared under K100221.

The **CONCISE,** (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lenses have the identical manufacturing process (lathe-cut versus lathe-cut) as the marketed Intelliwave3 (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens, cleared under K100221.

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Substantial Equivalence:

The following matrix illustrates the production method, lens function and material characteristics of the **CONCISE,** (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens, as well as the predicate devices.

Conclusions Drawn from Studies

Validity of Scientific Data

Several laboratories under Good Laboratory Practice regulations conducted toxicology studies, Microbiology, chemistry, shelf-life stability studies and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **CONCISE,** (efrofilcon A) Silicone Hydrogel Daily Wear Soft Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of Silicone Hydrogel, Daily Wear Soft Contact Lens. The benefits to the patient are the same as those for other Silicone Hydrogel contact lenses.

	CONCISE Soft, Silicone Hydrogel (efrofilcon A) New Device	IntelliWave[3], Silicone Hydrogel (efrofilcon A) predicate device. 510(k) K100221	CooperVision Biofinity (comfilcon A) predicate device. 510(k) K052560	Hydron Ltd. ActiFresh 400 (lidofilcon A) predicate device. 510(k) K983637
Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	same as predicate device	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	Daily wear, Silicone Hydrogel Soft (hydrophilic) contact lens	Daily wear, Silicone Hydrogel Soft (hydrophilic) contact lens	Daily wear, Silicone Hydrogel Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Production Method	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured	Cast Molded, mass produced	Lathe-Cut, custom manufactured
USAN name	efrofilcon A	efrofilcon A	comfilcon A	lidofilcon A
Water Content	74%	74%	48.0%	74.0%
Oxygen Permeability	60 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	60 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	128 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	28 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).
Specific Gravity	1.139	1.139	1.142	1.060

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbconcise Optical Group, LLC
c/o Mr. Martin Dalsing
Official Correspondent
Medvice Consulting, Inc.
806 Kimball Avenue
Grand Junction, CO 81501

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Re: K111267
Trade/Device Name: CONCISE, Silicone Hydrogel DW Soft Contact Lens (efrofilcon A)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: October 25, 2011
Received: October 26, 2011

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111267

INDICATIONS FOR USE

510(k) number: K111267

Device Name: **CONCISE, Silicone Hydrogel Daily Wear Soft Contact Lens (efrofilcon A)**

INDICATIONS FOR USE:

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Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111267